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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

1

of

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**Complete if Known**

Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
<i>U</i>	U1	4,818,527		Thornton et al.	04-04-1989	All
<i>U</i>	U2	5,100,662		Bolcsak et al.	03-31-1992	All
<i>U</i>	U3	5,158,769		Neurath et al.	10-27-1992	All
<i>U</i>	U4	4,235,877		Fullerton	11-25-1980	All
<i>U</i>	U5	4,428,941		Galibert et al.	01-31-1984	All
<i>U</i>	U6	4,487,715		Nilecki et al.	12-11-1984	All
<i>U</i>	U7	4,559,230		Milich et al.	12-17-1985	All
<i>U</i>	U8	4,599,231		Milich et al.	07-08-1986	All
<i>U</i>	U9	4,882,145		Thornton et al.	11-21-1989	All
<i>U</i>	U10	4,935,235		Rutter et al.	08-19-1990	All
<i>U</i>	U11	5,017,558		Vyas	05-21-1991	All
<i>U</i>	U12	5,019,386		Machida et al.	05-28-1991	All
<i>U</i>	U13	5,039,522		Neurath	08-13-1991	All
	U14					
	U15					
	U16					
	U17					

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7 <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
<i>DCW</i>	F1	EP	013 828	A1	Murray et al.	08-06-1980	All	
<i>DCW</i>	F2	EP	469 281	A1	Ferrari et al.	02-05-1992	All	
<i>DCW</i>	F3	EP	105 481	A1	Boothroyd et al.	04-18-1984	All	
<i>DCW</i>	F4	EP	431 327	B1	Jung et al.	06-12-1991	All	
<i>DCW</i>	F5	EP	534 615	A2	Vitiello et al.	03-31-1993	All	
<i>DCW</i>	F6	GB	2034323		Inst. Nat. Sante Rech. Med.	06-04-1980	All	
	F7	JP	161999					
	F8							
	F9							
	F10							

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Signature*Donna C. Wortman*Date  
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9/15/03

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Substitute for form 1440B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

Sheet	2	of	7
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**NON PATENT LITERATURE DOCUMENTS**

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R	R1	BERTOLETTI, A. <i>et al.</i> "Natural variants of cytotoxic epitopes are T-cell receptor antagonists for antiviral cytotoxic T cells" <i>Nature</i> , June 2, 1994, 369:407-410.	
R	R2	BICHKO <i>et al.</i> "Subtype ayw variant of hepatitis B virus" <i>FEBS Lett.</i> , 1985, 185:208-212.	
R	R3	BOWIE <i>et al.</i> "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions" <i>Science</i> , 1990, 247:1306-1310.	
R	R4	CARBONE <i>et al.</i> "Induction of Cytotoxic T Cells by Primary in vitro Stimulation with Peptides" <i>J. Exp. Med.</i> , 1988, 167:1767-1779.	
R	R5	DE MAGISTRIS, M.T. <i>et al.</i> "Antigen analog-major histocompatibility complexes act as antagonists of the T cell receptor" <i>Cell</i> , February 21, 1992, 68(4):625-634.	
R	R6	FALK <i>et al.</i> "Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules" <i>Nature</i> , May 1991, 351:290-296.	
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R	R8	HILLEMANN "Comparative Biology and Pathogenesis of AIDS and Hepatitis B Viruses: Related but Different" <i>AIDS Res. Hum. Retrovir.</i> , 1994, 10:1409-1419.	
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R	R10	KUMAR <i>et al.</i> "Amino acid variations at a single residue in an autoimmune peptide profoundly affect its properties" <i>PNAS USA</i> , 1990, 87:1337-1341.	
R	R11	LEWIN "When Does Homology Mean Something Else?" <i>Science</i> , 1987, 237:1570.	
R	R12	MILICH <i>et al.</i> "Immune Response to Hepatitis B Virus Core Antigen (HBcAg): Localization of T Cell Recognition Sites Within HBcAg/HBeAg" <i>J. Immunol.</i> , 1987, 139:1223-1231.	
R	R13	NAYERSINA <i>et al.</i> "HLA A2 Restricted Cytotoxic T Lymphocyte Responses to Multiple Hepatitis B Surface Antigen Epitopes during Hepatitis B Virus Infection" <i>J. Immunol.</i> , 1991, 150:4659-4671.	

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**INFORMATION DISCLOSURE  
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Sheet

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**Complete if Known**

Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R14	REECK <i>et al.</i> "Homology in Proteins and Nucleic Acids: A Terminology Muddle and a Way out It" <i>Cell</i> , 1987, 50:667.	
	R15	RUPPERT, J. <i>et al.</i> "Prominent role of secondary anchor residues in peptide binding to HLA-A2.1 molecules" <i>Cell</i> , 1993, 74(5):929-937.	
	R16	TONG <i>et al.</i> "Active Hepatitis B Virus Replication in the Presence of Anti-HBe is Associated with Viral Variants Containing an Inactive Pre-C Region" <i>Virology</i> , 1990, 176:596-603.	
	R17	VITIELLO, A. <i>et al.</i> "Development of a lipopeptide-based therapeutic vaccine to treat chronic HBV infection. I. Induction of a primary cytotoxic T lymphocyte response in humans" <i>J. of Clin. Invest.</i> , January 1995, 95(1):341-349.	
	R18	GREENSTEIN, J.L. <i>et al.</i> "A universal T cell epitope-containing peptide from hepatitis B surface antigen can enhance antibody specific for HIV gp120" <i>J. Immunology</i> , 1992, 148:3970-3977.	
	R19	WATARI, E. <i>et al.</i> "A synthetic peptide induces long-term protection from lethal infection with herpes simplex virus 2" <i>J. Exp. Med.</i> , 1987, 165(2):459-470.	
	R20	HOPP, T.P. "Immunogenicity of a synthetic HBsAg peptide: enhancement by conjugation to a fatty acid carrier" <i>Mol. Immunol.</i> , 1984, 21(1):13-16.	
	R21	BESSLER, W.G. <i>et al.</i> "The synthetic analog of bacterial lipoprotein are potent immunoadjuvants in combination with or covalently linked to antigen" <i>Prog. Leukocyte Biol.</i> , 1986, 5:337-344.	
	R22	PARKER <i>et al.</i> "Peptide Binding to HLA-A2 and HLA-B27 Isolated from <i>E. coli</i> " <i>J. Biol. Chem.</i> , 1992, 267:5451-5459.	
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	R24	FERRARI <i>et al.</i> "Identification of Immunodominant T Cell Epitopes of the Hepatitis B Virus Nucleocapsid Antigen" <i>J. Clin. Invest.</i> , 1991, 88:214-222.	
	R25	ROITT <i>et al.</i> "Immunology", 3 <sup>rd</sup> Ed., Mosby, St. Louis, p. 4.14, 1993.	
	R26	<del>REHERMANN <i>et al.</i> "The cytotoxic T lymphocyte response to multiple hepatitis B virus polymerase epitopes during and after acute viral hepatitis" <i>J. Exp. Med.</i>, March 1, 1995, 181(3):1047-1058.</del>	

Examiner Signature		Date Considered	8/15/03
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		Application Number	09/863,054
		Filing Date	May 21, 2001
		First Named Inventor	Francis V. Chisari
		Group Art Unit	1648
		Examiner Name	Donna C. Wortman
		Attorney Docket Number	EPI-T101D4

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	R27	ZINKERNAGEL <i>et al.</i> "The Lymphoregulatory System in Triggering Virus Plus Self-Specific Cytotoxic T Cells: Evidence for T Help" <i>J. Exp. Med.</i> , 1978, 147:897-911.	
	R28	VON BOEHMER <i>et al.</i> "Distinct Ir Genes for Helper and Killer Cells in the Cytotoxic Response to H-Y Antigen" <i>J. Exp. Med.</i> , November 1979, 150:1134-1142.	
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	R30	WIDMER <i>et al.</i> "Antigen-derived helper cell-independent cloned cytolytic T lymphocytes" <i>Nature</i> , 1981, 294:750-752.	
	R31	LERNER <i>et al.</i> "Chemically synthesized peptides predicted from the nucleotide sequence of the hepatitis B virus genome elicit antibodies reactive with the native envelope protein of Dane particles" <i>Proc. Natl. Acad. Sci. USA</i> , June 1981, 78:3403-3407.	
	R32	BHATNAGAR <i>et al.</i> "Immune response to synthetic peptide analogues of hepatitis B surface antigen specific for the determinant" <i>PNAS USA</i> , July 1982, 79:4400-4404.	
	R33	MONDELLI <i>et al.</i> "Specificity of T lymphocyte cytotoxicity to autologous hepatocytes in chronic hepatitis B virus infection: evidence that T cells are directed against HBV core antigen expressed on hepatocytes" <i>J. Immunol.</i> , December 1982, 129:2773-2778.	
	R34	VON BOEHMER <i>et al.</i> "Autonomously proliferating K/D-restricted cytolytic T cell clones" <i>Eur. J. Immunol.</i> , 1983, 12:178-179.	
	R35	NEURATH <i>et al.</i> "Specificity of antibodies elicited by a synthetic peptide having a sequence in common with a fragment of a virus protein—The hepatitis B surface antigen" <i>Develop. Biol. Standard</i> , 1983, 54:103-112.	
	R36	VON BOEHMER <i>et al.</i> "Lyt-2 T cell-independent functions of Lyt-2+ cells stimulated with antigen or concanavalin A" <i>J. Immunol.</i> , July 1984, 133:59-64.	
	R37	MILICH <i>et al.</i> "Immunogenetics and cellular correlates of the immune response to hepatitis B surface antigen determinants" <i>Adv. Hepatitis Res.</i> , Masson, N.Y., N.Y. USA 91-109, 1984.	
	R38	FUJII <i>et al.</i> "Peptide Chemistry 1983" published 1984 by Protein Research Foundation (OSAKA), pp.215-220.	
	R39	SPRENT <i>et al.</i> "Properties of purified T cell subsets" <i>J. Exp. Med.</i> , December 1985, 162:2068-2088.	

Examiner Signature		Date Considered	9/28/03
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Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

Sheet 5 of 7

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	R40	TOWNSEND <i>et al.</i> "The epitopes of influenza nucleoprotein recognized by cytotoxic T lymphocytes can be defined with short synthetic peptides" <i>Cell</i> , March 28, 1988, 44:959-968.	
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	R42	BULLER <i>et al.</i> "Induction of cytotoxic T-cell responses in vivo in absence of CD4 helper cells" <i>Nature</i> , July 2, 1987, 328:76-79.	
	R43	MILICH <i>et al.</i> "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site" <i>Nature</i> , October 9, 1987, 329:547-549.	
	R44	MONDELLI <i>et al.</i> "Definition of hepatitis B virus (HBV)-specific target antigens recognized by cytotoxic T cells in acute HBV infection" <i>Clin. Exp. Immunol.</i> , 1987, 68:242-250.	
	R45	MILICH <i>et al.</i> "Hepatitis B synthetic immunogen comprised of nucleocapsid T-cell sites and an envelope B-cell epitope" <i>PNAS USA</i> , March 1988, 85:1610-1614.	
	R46	CELIS <i>et al.</i> "Recognition of hepatitis B surface antigen by human T lymphocytes" <i>J. Immunol.</i> , March 15, 1988, 140:1808-1815.	
	R47	MOORE <i>et al.</i> "Introduction of soluble protein into the Class I pathway of antigen processing and presentation" <i>Cell</i> , September 9, 1988, 54:777-785.	
	R48	MILICH <i>et al.</i> "Comparative Immunogenicity of Hepatitis B virus core and E antigens" <i>J. Immunol.</i> , November 15, 1988, 141:3617-3624.	
	R49	GOTCH <i>et al.</i> "Recognition of influenza A matrix protein by HLA-A2-restricted cytotoxic T lymphocytes" <i>J. Exp. Med.</i> , December 1988, 163:2045-2057.	
	R50	MILICH "T- and B-cell recognition of hepatitis B viral antigens" <i>Immunol. Today</i> , 1988, 9:380-386.	
	R51	HAYASHI <i>et al.</i> "Studies on peptides CLXVI. Solid-phase synthesis and immunological properties of fragment peptides related to human hepatitis B virus surface antigen (HBsAg) and its pre-S2 gene" <i>Chem. Pharm. Bull.</i> , 1988, 36(12):4993-4994.	
	R52	BRACIALE <i>et al.</i> "Class I major histocompatibility complex-restricted cytolytic T lymphocytes recognize a limited number of sites on the influenza hemagglutinin" <i>PNAS USA</i> , January 1989, 86:277-281.	

Examiner Signature		Date Considered	7/28/03
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Sheet 6 of 7

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Group Art Unit	1648
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	R53	ISHIOKA <i>et al.</i> "Induction of class-I-MHC-restricted peptide-specific cytolytic T-lymphocytes by peptide priming in vivo" <i>J. Immunol.</i> , August 15, 1989, 143:1094-110.	
R	R54	KLAVINSKIS <i>et al.</i> "Molecularly engineered vaccine which expresses an immunodominant T-cell epitope induces cytotoxic T lymphocytes that confer protection for lethal virus infection" <i>J. Virol.</i> , October 1989, 63:4311-4316.	
R	R55	BEVAN "Stimulating killer cells" <i>Nature</i> , November 30, 1989, 342:478-479.	
	R56	<del>DERES <i>et al.</i> "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine" <i>Nature</i>, November 30, 1989, 342:561-564.</del>	
R	R57	TAM <i>et al.</i> "Vaccine engineering" Enhancement of immunogenicity of synthetic peptide vaccines related to hepatitis in chemically defined models consisting of T- and B-cell epitopes" <i>PNAS USA</i> , December 1989, 86:9084-9088.	
R	R58	CHISARI <i>et al.</i> "Hepatitis B virus structure and biology" <i>Microbial Pathogenesis</i> , 1989, 6:311-325.	
R	R59	MORIYAMA <i>et al.</i> "Immunobiology and pathogenesis of hepatocellular injury in hepatitis B virus transgenic mice" <i>Science</i> , April 20, 1990, 248:361-364.	
R	R60	AICHELE <i>et al.</i> "Antiviral cytotoxic T cell response induced by in vivo priming with a free synthetic peptide" <i>J. Exp. Med.</i> , May 1990, 171:1815-1820.	
R	R61	AGGARWAL <i>et al.</i> "Oral Salmonella: Malaria Circumsporozoite recombinants induce specific CD8 <sup>+</sup> cytotoxic T cells" <i>J. Exp. Med.</i> , October 1990, 172:1083-1090.	
R	R62	VAN BLEEK <i>et al.</i> "Isolation of an endogenously processed immunodominant viral peptide from the class II-H-2K <sup>b</sup> molecule" <i>Nature</i> , November 15, 1990, 348:213-216.	
	R63	<del>ROTZSCHKE <i>et al.</i> "Isolation and analysis of naturally processed viral peptides as recognized by cytotoxic T-cells" <i>Nature</i>, November 15, 1990, 348:252-254.</del>	
R	R64	GOLVANO <i>et al.</i> "Polarity of immunogens: implications for vaccine design" <i>Eur. J. Immunol.</i> , 1990, 20:2363-2366.	
R	R65	ISHIOKA <i>et al.</i> "Class I MHC-restricted, peptide-specific cytotoxic T lymphocytes generated by peptide priming in vivo" <i>Vaccines 90</i> , Cold Spring Harbor Press, p. 7-11, 1990.	

Examiner  
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**Complete if Known**

Application Number	09/863,054
Filing Date	May 21, 2001
First Named Inventor	Francis V. Chisari
Group Art Unit	1648
Examiner Name	Donna C. Wortman
Attorney Docket Number	EPI-T101D4

Sheet 7 of 7

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R66	CAST <i>et al.</i> "Protection against lethal Sendai virus infection by in vivo priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide" <i>PNAS USA</i> , March 1991, 88:2283-2287.	
	R67	SCHUMACHER <i>et al.</i> "Peptide selection by MHC class I molecules" <i>Nature</i> , April 25, 1991, 350:703-706.	
	R68	<del>BERTOLETTI <i>et al.</i> "HLA class I-restricted human cytotoxic T-cells recognize endogenously synthesized hepatitis-B nucleocapsid-antigen" <i>PNAS USA</i>, December 1991, 88:10445-10449.</del>	
	R69	SAROE <i>et al.</i> "Induction of antibodies against peptide Hapten does not require covalent linkage between Hapten & class II presentable T helper peptide" <i>Eur. J. Immunol.</i> , 1991, 21:1555-1558.	
	R70	CASELL <i>et al.</i> "Linked recognition of helper and cytotoxic antigenic determinants for the generation of cytotoxic T lymphocytes" <i>Ann. N.Y. Acad. Sci.</i> , 1991, pp. 51-60.	
	R71	<del>PENNA <i>et al.</i> "Hepatitis B virus (HBV)-specific cytotoxic T-cell (CTL) response in humans: Characterization of HLA class II-restricted CTLs that recognize endogenously synthesized HBV envelope antigens" <i>J. Virol.</i>, February 1992, 66:1193-1198.</del>	
	R72	GUILHOT <i>et al.</i> "Hepatitis B virus (HBV)-specific cytotoxic T-cell response in humans: Production of target cells by stable expression of HBV-encoded proteins in immortalized human B-cell lines" <i>J. Virol.</i> , May 1992, 66:2670-2678.	
	R73	WAKITA <i>et al.</i> "Gamma-interferon production response to hepatitis B core protein & synthetic peptides in patients with chronic hepatitis B virus infection" <i>Digestion</i> , 1990, 47:149-155.	
	R74		
	R75		
	R76		
	R77		
	R78		

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